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September 15, 2004

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Mr. John H. Robertus
Executive Officer
San Diego Regional Water Quality Control Board
9174 Sky Park Court, Suite 100
San Diego, CA 92123-4340

Re: Tentative Order No. R9-2004-0154 — Supplemental Comments of Duke
Energy South Bay, LLC

Dear Mr. Robertus:

This letter is submitted on behalf of Duke Energy South Bay, LLC (“Duke Energy”) in connection with the renewal of the NPDES permit for the South Bay Power Plant (“SBPP”) (Tentative Order No. R9-2004-0154). At the hearing on September 8, 2004, the Regional Board indicated that the record would remain open through September 15, 2004 for the submission of additional written comments on issues that were discussed at the hearing. These include:

- Implementation of the new effluent limitations for copper
- Clean Water Act section 316(a) compliance and relocation of the compliance monitoring point for temperature
- Clean Water Act section 316(b) compliance
- Dissolved oxygen
- Special Sunset Study

At the request of Regional Board staff, the Board members also provided guidance to staff concerning possible revisions to the Tentative Order with respect to each of these issues. In some cases, the Board’s guidance appeared reasonably definitive, while in other cases, the Board members had many questions of a technical nature and were unable to provide specific direction to staff. Duke Energy’s comments reflect its understanding of the guidance that was offered by the Board members during their

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deliberations on the Tentative Order and its view that further consideration of scientific evidence and other relevant information concerning thermal effects is needed before a final decision can be rendered. The Regional Board continued the matter to its hearing in November 2004, at which time it expects to act on the permit.

Implementation of the new effluent limitations for copper

As explained at the hearing and in its previous comment letter dated August 18, 2004, due to circumstances entirely beyond its control, Duke Energy is unable to comply with the new water quality-based effluent limitations (“WQBELs”) for copper that are contained in the Tentative Order. While the SBPP’s discharge contains trace amounts of copper from corrosion of copper tubes in plant equipment, concentrations of copper attributable to this source are substantially below the proposed effluent limitations. However, available water quality monitoring data indicates that ambient concentrations of copper in San Diego Bay — unrelated to SBPP — exceed, or are likely to exceed, the effluent limitations in the Tentative Order. Because bay water is drawn into the plant for cooling and is discharged without treatment, Duke Energy would be unable to comply with the effluent limitations if they are made effective immediately upon adoption of the permit. Given the large amount of water that is used by the plant (up to 601 MGD) and the trace amounts of copper in the water (even taking ambient concentrations into account), treatment of the water prior to discharge is not technically or economically feasible.

Duke recognizes that the copper limits are a function of the California Toxics Rule (“CTR”) and are based upon the reasonable potential analysis conducted by staff, as set forth in the State Policy for Implementation of Toxic Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (“SIP”). However, the SIP explicitly provides that:

Based on an *existing discharger’s request and demonstration that it is *infeasible for the discharger to achieve immediate compliance with a CTR criterion, or with an effluent limitation based on a CTR criterion, the RWQCB may establish a compliance schedule in an NPDES permit. SIP, section 2.1 (emphasis added).

Under the SIP, “infeasible” means “not capable of being accomplished in a successful manner within a reasonable period of time, taking into account economic, environmental, legal, social, and technological factors.” SIP, Appendix 1-3.

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SBPP is an existing discharger, and Duke Energy has requested that a five-year compliance schedule be included in its NPDES permit, based on the acknowledged infeasibility of achieving immediate compliance with the copper limits. The CTR allows compliance schedules of up to five years in length to be included in a permit. 40 CFR § 131.38(e). The preamble to the CTR also states that “[t]he discharger’s opportunity to obtain a compliance schedule occurs when the existing permit for that discharge is issued, reissued or modified to contain more stringent limits based on the water quality criteria in today’s rule.” 65 Fed. Reg. 31682, 31704.

Federal law also requires that the state water quality control plan for the affected water body provide for the inclusion of compliance schedules in NPDES permits. *Matter of Star-Kist Caribe, Inc.*, 1990 WL 324290 (April 16, 1990). Such authorization is contained in the Water Quality Control Plan for the San Diego Basin (“Basin Plan”). In Chapter 4, Implementation, the Basin Plan states that “[a] standard NPDES permit typically includes the following elements: [including, among other things,] “Compliance Schedules: Time schedules for completion of activities to achieve compliance with permit conditions . . .” (Basin Plan, p.4-8). Accordingly, there is no legal impediment to the inclusion of a compliance schedule in Duke Energy’s NPDES permit for SBPP. Because the Basin Plan does not speak to the length of compliance schedules, it is reasonable to look to the CTR to establish the allowable duration.

Duke Energy recognizes that the Regional Board has other options available to it, namely time schedule orders under Water Code section 13300 and cease and desist orders under section 13301. Duke believes very strongly that neither of these options is appropriate in the circumstances because they are both types of enforcement orders and presume a degree of malfeasance or unwillingness on the discharger’s part. The CTR, the SIP and the Basin Plan each recognize that an existing discharger may not be able to achieve immediate compliance with a new, more stringent WQBEL — such as is the case here — and that the effectiveness of such WQBELs should be delayed by up to five years in order to give the discharger a reasonable opportunity to take steps to come into compliance *before* being found in violation. In other words, the compliance process is a permitting issue, not an enforcement issue. It is both inappropriate and inequitable to use an enforcement mechanism in this context.

Based on the Board members’ comments at the September 8 hearing (particularly those of Board member Ghio), Duke Energy believes that the Board endorsed the inclusion of a compliance schedule in the permit and provided staff with direction to proceed in this manner. This outcome ensures consistency with Duke Energy’s corporate policy, which does not allow it to operate in violation of applicable permit conditions.

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Duke Energy would also like to comment briefly on the variety of options that may be available under the SIP for achieving compliance with the copper limit. Because technical compliance with the WQBEL, as currently drafted, is not technically or economically feasible under any circumstances, a regulatory or administrative solution will need to be found. Possibilities include the following:

- Under section 2.2.2 of the SIP, the Regional Board is not required to include a WQBEL in the permit if there is insufficient data upon which to conduct a reliable reasonable potential analysis. In lieu of the limits currently contained in the Tentative Order, Duke Energy could be required to conduct receiving water monitoring over the next couple of years to determine whether ambient concentrations of copper exceed the CTR criterion to a degree that is statistically significant. If ambient copper concentrations do not exceed the CTR criterion, WQBELs may not be required.
- Evaluate the feasibility or usefulness of developing a site-specific translator for purposes of calculating total recoverable copper limits from dissolved copper criteria.
- Evaluate whether use of the water-effect ratio would be useful in deriving a WQBEL that is achievable.
- Develop a site-specific objective for copper for south San Diego Bay, similar to the process that was utilized for the southernmost portion of San Francisco Bay. This option would require an amendment to the Basin Plan.
- Grant a site-specific exception to the SIP provision that prohibits the award of intake credits in circumstances where ambient concentrations exceed the applicable criterion. Section 5.3 of the SIP allows case-by-case exceptions to meeting a priority pollutant criterion (such as copper) where it is determined that the exception will not compromise protection of waters for beneficial uses and the public interest will be served.

With respect to this last option, it is noted that the SBPP has been designated by the California Independent System Operator as a “reliability must-run” (“RMR”) facility. The entire output of the plant (689 MW) is under an RMR contract, and the ability of the plant to maintain its current generating capacity is critical to maintaining reliable load serving capability in the San Diego Area. There is no evidence that copper concentrations in the south San Diego Bay are compromising beneficial uses (despite

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occasional exceedances of the CTR criterion), and the compelling public interest in ensuring adequate power supplies would be served by the granting of an exception.

Clean Water Act section 316(a) compliance and relocation of the compliance monitoring point for temperature

As required by the May 2002 section 13267 letter, Duke Energy conducted studies of the SBPP's thermal discharge for purposes of demonstrating compliance with Clean Water Act section 316(a). Under section 316(a), effluent limitations for the thermal component of a discharge must ensure "the protection and propagation of a balanced, indigenous population of shellfish, fish, and wildlife" in the receiving water body (the balanced indigenous community, or "BIC," standard). The BIC standard is an inherently narrative standard and, as such, is subject to interpretation in any given set of facts. Nevertheless, the standard contemplates that some level of impact will occur and is acceptable under the law. The question is one of extent and degree.

Prior studies of the SBPP discharge documented certain effects associated with the thermal plume, but concluded that such effects were not significant. The most recent studies were conducted by Tenera Environmental and Merkel & Associates, both of whom have extensive experience in identifying and evaluating the biological effects of thermal discharges. The reports are based on extensive data collected during the hottest months of the year and employ well-established scientific methodologies for measurement and evaluation of observed effects. Based on these data, Tenera and Merkel reached two major conclusions: (1) that the SBPP's discharge has an effect on the benthic community in the immediate vicinity of the discharge, but that these effects are not ecologically significant; and (2) that the distribution of eelgrass in the discharge channel might be a little (6%) more extensive, or have a longer growing season, absent the temperature and turbidity associated with the plant's discharge.

Based on extensive and current scientific data collected from San Diego Bay and the discharge channel, Duke Energy's technical experts have concluded that, in their professional judgment, the thermal effects of the SBPP discharge do not violate the BIC standard and have not resulted in a degradation of beneficial uses. Reports submitted by the Bay Council assert the opposite result, based solely on old laboratory studies and literature reviews conducted by an English firm, Pisces Conservation Ltd., and Dr. Richard Ford, Professor Emeritus at San Diego State University. Duke Energy believes that Regional Board staff and the Board itself must consider fully the relative scientific merit and weight of the recent Board-mandated studies conducted by Tenera and Merkel and the theoretical studies and literature reviews submitted by Bay Council. While

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reasonable minds may disagree over how to interpret the facts and findings of the recent SBPP thermal discharge studies, the Bay Council's consultants did not base their opinions on the data reported in these studies, or even on similar data from comparable studies. Duke Energy believes there are important scientific and statistical differences between these studies that must be factored into an assessment of whether the BIC standard is being achieved and whether beneficial uses are being protected. The most striking and important of the scientific differences are summarized in the attached Technical Addendum to this letter.¹ In short, the conclusions in the Pisces and Ford reports should not be accepted at face value.

Duke Energy is concerned that staff has given equal weight to its 2003 316(a) studies and the competing reports submitted by the Bay Council, without considering their relative scientific value in understanding actual conditions in the discharge channel. More specifically, staff's recommendation to move the temperature compliance monitoring point from S1 to S2 (the property line) appears to be driven by a foregone conclusion that the thermal effects of the plant, by virtue of the fact that they are discernible, violate the BIC standard and represent an unacceptable degradation of beneficial uses. Duke Energy strongly disagrees with this conclusion and does not believe it is supported by substantial evidence.

The Board-mandated studies demonstrate that a wide variety of balanced indigenous communities exist in San Diego's south bay. While all aspects of these communities are not identical to what might exist if the plant were not operating, that is not the legal test. The Water Code prohibits alteration of water quality to a degree that unreasonably affects beneficial uses (Water Code, § 13050(l)). Section 13241 of the Water Code explicitly recognizes that "it may be possible for the quality of water to be changed to some degree

¹ The 2003 316(a) report conducted on behalf of Duke Energy draws on results from many more stations in the discharge area and thus provides a better statistical representation of the true effects of the SBPP discharge. This level of detail on the discharge was not available in the past reports reviewed by Dr. Ford. Ford only considered the field data he collected from his and other past thermal effects studies and did not review the 2003 study findings or compare them in his review. Further, the information in Ford's report is not presented in a manner that allows comparison with the results from the 2003 study. Further, Given that Ford did not review (or at least did not report on) the results of the 2003 studies, conclusion he reaches with respect to SBPP discharge effects are necessarily incomplete.

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without unreasonably affecting beneficial uses.” It follows from this that all beneficial uses do not need to be achieved uniformly across the entire water body. A reasonable degree of variation is permissible. This is especially true where, as in the case of San Diego Bay, the Basin Plan identifies potentially competing beneficial uses — industrial service supply (IND) and marine habitat (MAR). In such circumstance, the Regional Board must strike an appropriate balance between the beneficial uses, and is without authority to elevate one beneficial use to the detriment of another.

As indicated at the September 8 hearing, Duke acknowledges that effluent limitations are imposed at the point of discharge unless a mixing zone or zone of initial dilution (“ZID”) has been established, in which case the point of compliance is at the edge of the mixing zone or ZID. 40 CFR § 122.45(a). However, effluent samples collected for purposes of compliance monitoring are also required to be representative of the discharge. 40 CFR § 122.41(j)(1). In the case of the SBPP, cooling water is discharged from four separate pipes, making collection of a representative sample more complex. Duke Energy testified that it is not wed to S1 as the only appropriate compliance monitoring point. However, any decision to relocate the temperature compliance monitoring point must be based on a finding, supported by substantial evidence in the record, that a representative sample of the combined cooling water discharge can be collected at the new location.

With respect to the temperature limits that will apply at the new monitoring location, the limits must be based on a determination, supported by substantial evidence in the record, that they are necessary for the reasonable protection of beneficial uses and to support a balanced indigenous community in south San Diego Bay. As Duke Energy indicated at the hearing and in its previous comment letter, it may be necessary to increase the plant’s current temperature limits (15°ΔT average daily; 25°ΔT instantaneous maximum) in order to preserve the plant’s current generating capacity (the plant’s rated capacity is already restricted by the current temperature limits at S1). The current limits may not be imposed at the property line (or at some other location landward of S1) unless they are determined to be necessary for the reasonable protection of beneficial uses. Such a determination must be supported by substantial evidence in the record. At this point, there is no evidence in the record which supports the conclusion that the thermal effects of the SBPP’s discharge, as described in the recent 316(a) studies as well as in past studies, cross a threshold of “degradation” or unreasonably affect beneficial uses. In summary, Duke Energy believes that the current temperature control regime for the plant is protective of beneficial uses and may not be made more stringent unless findings are made as to the necessity for such changes.

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Clean Water Act section 316(b) compliance

Duke Energy believes that the results of the recent 316(b) study demonstrate that the construction and operation of SBPP's cooling water intake structure represents Best Technology Available ("BTA"), as interpreted by the U.S. Environmental Protection Agency over the past 25 years. EPA recently promulgated new BTA regulations for existing facilities (the Phase II regulations) which provide a range of new compliance strategies for reducing impingement and entrainment effects associated with cooling water intake structures. The Phase II rules became effective on September 7, 2004, and provide existing facilities with up to three and a half years to come into compliance with the new standard. In the meantime, the permit may be renewed on the basis of BTA findings made in accordance with pre-existing EPA guidance and applicable case law.

Under this pre-existing body of law, alternative cooling technologies that are not technically feasible (i.e., not available) or whose cost of implementation would be "wholly disproportionate" to the environmental benefits to be gained are not considered BTA. In response to the May 2002 section 13267 letter, Duke Energy retained Tenera Environmental to study the impingement and entrainment effects associated with operation of the cooling water intake structure at SBPP. Tenera concluded that these effects were not significant in terms of the stability of the affected populations and thus did not constitute an "adverse environmental impact." Contrary to the Bay Council's assertion, principles of compensatory reserve are a well-recognized and long-accepted aspect of any analysis of impingement and entrainment effects. Notwithstanding its conclusion that fish and shellfish populations are not significantly affected by the plant, Tenera investigated a wide array of alternative cooling technologies and determined in each case that the cost of implementing the technology was wholly disproportionate to the benefit to be gained. This same conclusion would pertain whether Tenera assumed an amortization period of five years (the anticipated remaining operating years, assuming SBPP's reliability must-run status is no longer in effect) or a longer period (e.g., 20-30 years). In either case, the cost of retrofitting the plant would be wholly disproportionate to the environmental benefit that would be gained thereby. As such, the existing system is still considered BTA.

The Phase II rules allow restoration measures to be used to offset impingement and entrainment effects. A similar provision in the Phase I rules for new facilities was recently invalidated by the U.S. Court of Appeals for the Second Circuit (*RiverKeeper, Inc. et al. v. EPA*). The Phase II rules, including the provisions regarding restoration measures, have already been challenged and the case is pending in the Ninth Circuit Court of Appeals. Although EPA believes that the use of restoration measures for



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existing facilities is defensible, and that the law makes the necessary distinction between existing and new facilities (see 69 Fed. Reg. 41576, 41625-41629), it remains to be seen whether this aspect of the Phase II rules will be upheld by the court. Duke Energy does not believe that the Water Code independently authorizes regional boards to require mitigation of entrainment or impingement effects associated with cooling water intake structures, although dischargers may, or course, voluntarily agree to the inclusion of such requirements in an NPDES permit.

Dissolved oxygen

Staff testified at the September 8 hearing that it lacked sufficient information upon which to establish a dissolved oxygen ("DO") limit for the SBPP. Duke Energy agrees with this conclusion, and notes further that the DO objective in the Basin Plan is applicable to inland surface waters only. The Regional Board did not provide any contrary guidance at the September 8 hearing.

Special Sunset Study

Based on guidance provided by the Regional Board at the September 8 hearing, Duke Energy understands that the NPDES permit will not contain a requirement to perform the Special Sunset Study. As James White indicated at the hearing, Duke Energy is committed to working with Regional Board staff and the resource agencies to ensure that the shutdown of the plant (whenever it occurs) is conducted in an environmentally responsible manner, with due consideration to the green sea turtles in the discharge channel.

Thank you for your consideration of these comments.

Very truly yours,

A handwritten signature in cursive script, reading "Margaret Rosegay".

Margaret Rosegay

Attach.

cc: Members of the Board



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cc: Randy Hickok
James White
Jane Pearson, Esq.

SELECTED COMMENTS ON PISCES REPORT RELATING TO RELOCATION OF THE DISCHARGE COMPLIANCE POINT

REPORT ENTITLED: “Notes on the South Bay Power Plant (SBPP) 316 a & b application.”
R M H Seaby, Pisces Conservation Ltd., Version 3, 29 July 2004, prepared for the San Diego Bay Council and submitted to the San Diego Regional Water Quality Control Board August 18, 2004.

Location	PISCES Report	Duke Energy Comment
Page 4	“The SBPP extracts a significant portion of the volume of the South San Diego Bay each day (approximately 20%)...”	This statement is incorrect. Even if the power plant were operating at maximum permitted flow (i.e., all pumps on all units running at 100 percent capacity), it would use only 1.06% of the volume of the South San Diego Bay each day.
Page 9	The report states that the warming and rapid cooling of the effluent discharge when the plant ramps up and down has an “important” effect on benthic communities.	Ford’s report (also submitted by Bay Council) suggests that fluctuating temperatures have a beneficial effect on thermal resistance (see p.20 of Ford report). This contradicts the implication in the Pisces report.
Page 9	The report concludes with respect to the thermal discharge that “all that can really be stated with certainty is that the sampling stations show considerable variability and that the sampling stations nearest the outfall are <u>different</u> from some that are further away.” (emphasis added)	Duke Energy agrees with Pisces conclusion that there are differences in species diversity and abundance at the different sampling stations. Pisces does not describe these differences as “significant” or “adverse.” The Pisces report does not provide evidence that would support a finding that marine beneficial uses are being adversely affected by the SBPP discharge. “Different” is not tantamount to “degraded.”
Page 10	The report notes that the aggregation of fish in the vicinity of the plant’s outfalls “...is a commonly observed feature usually linked to the presence of food in the form of debris...that [has] passed through the station.”	The abundance of fish in the discharge area supports beneficial uses by providing food for birds and other animals that inhabit or utilize the area. Duke Energy does not believe this condition constitutes an adverse effect.

Page 10	The report notes that “the currents produced by cooling water discharges also offer a situation where faster swimming predatory fish can hold an appreciable advantage over their prey.”	This statement is not germane. The majority of fish reported in the SBPP discharge area feed on plankton, not on other fish.
Page 16	The report states that “[e]ven if species can live within this [discharge] zone, they <u>might be</u> living sub-optimally and <u>possibly</u> not be able to reproduce.” (emphasis added)	The PICES report does not provide any scientific basis or observations to support these speculations.
Page 16	The report states that “[o]ther outfalls have been shown to reduce the diversity of the invertebrates in the sediments,” citing Morro Bay, California as an example, with reference to an unnumbered figure from an unpublished report by Adams from 1969. ²	Tenera is familiar with the referenced study. The figure is from a 25-year old siting study for the Diablo Canyon nuclear power plant. This study was prepared by PG&E for the Atomic Energy Commission (now the Nuclear Regulatory Commission). The study was a hypothetical extrapolation of data for the purposes of estimating the potential effects of Diablo Canyon’s cooling water discharge. This study has since been replaced by actual data and findings from DCPD and Morro Bay cooling water discharge studies conducted over the intervening decades. ³

² Adams, J. R., D. G. Price and F. L. Clogston. 1974. An evaluation of the effect of Morro Bay Power Plant cooling water discharge on the intertidal macroinvertebrate community. PG&E, Department of Engineering Research, San Ramon, California. 32 pp.

Pacific Gas and Electric Company (PG&E). 1973. An evaluation of the effect of cooling water discharges on the beneficial uses of receiving waters at the Morro Bay Power Plant. San Francisco, CA.

³ In 2001 Tenera prepared the Morro Bay Power Plant Modernization Project Thermal Discharge Assessment Report for Duke Energy Morro Bay, LLC. This report was submitted to the California Energy Commission, the Central Coast Regional Water Quality Control Board, the California Department of Fish and Game, and the California Coastal Commission..

SELECTED COMMENTS ON FORD REPORT RELATING TO RELOCATION OF THE DISCHARGE COMPLIANCE POINT

REPORT ENTITLED: *“Recommended Options for Maximum Water Temperature Limits and Minimum Dissolved Oxygen Limits at a Compliance Point for Discharges from the South Bay Power Plant in San Diego Bay, Necessary to Protect Beneficial Uses.” Prepared by Richard F. Ford, Ph.D. for the San Diego Bay Council, and submitted to the San Diego Regional Water Quality Control Board August 18, 2004.*

Location	Ford Report	Comment
Figure 1 (p. 2), Figure 2 (p. 3), Figure 3 (p. 4), Figure 4 (p. 4) and Figure 5 (p. 4).	Each of these figures is referenced in the report, but is not provided.	These omissions severely limit the usefulness of this report in determining the effects of the SBPP discharge.
Page 17 and throughout report	The report states that “Merino (1981) found that annual mortality rates of <i>S. rosaceus</i> were significantly higher at stations within the inner thermal plume (Stations D2 –D7)...”	The referenced station locations are missing from report. In addition, the author does not provide any description or discussion of what is meant by the “inner thermal plume”. The locations cited by the author in his analysis of potential thermal effects are essential to any meaningful comparison of differences between Duke Energy’s and the author’s interpretation of discharge effects.

Page 7	The report notes that statistical comparisons during the years 1968-1973 suggested that species abundance and diversity remained relatively stable over time. The report further notes that with the addition of Generating Unit 4, the characteristics of the thermal discharge “had not resulted in major shifts in the numbers, diversity, or standing crop or plant and invertebrate species that form major components of the subtidal community.”	These conclusions support and are consistent with Duke Energy’s belief that beneficial uses in the discharge channel are being adequately protected and that a balanced indigenous community exists in the discharge area.
Page 11	The report notes that “... the species composition, relative abundances, and biomass of the infauna” in the study area have remained very much the same over the 21-year period from in 1968 – 1989.	Ford reviewed a wide range of studies of the SBPP discharge over a 35-year period. These studies appear to be consistent with the 316(a) study recently completed by Duke Energy. There is nothing in the Ford report, however, which indicates that the author reviewed the 2003 studies conducted by Tenera and Merkel on behalf of Duke Energy.
Page 9	There were no statistically significant differences for numbers and diversity of species between the outer discharge and control areas in either January or April 1973.	Ford reports that there were no statistical differences between the outer discharge and control areas, but omits the single inner discharge area station comparison. Since Ford has only a single inner discharge station (Station E5) to statistically represent the entire area enclosed by the wildlife refuge breakwater and shoreline, any conclusions about temperature differences that he draws are of questionable value.
Page 10	In discussing the results of monitoring data during the 18-year period 1977-1994, Ford concludes that “these elevated biomass values [in the near-field outside the cooling channel] may represent a disturbance modification effect on the infauna due to increased growth and reproduction.”	The author implies, but fails to explain how, increased biomass production constitutes an adverse environmental impact. Most ecosystems benefit from reasonable increases in food supply.

<p>Page 16</p>	<p>The report notes that “Merino (1981) found that reproduction of <i>S. rosaceus</i> and <i>T. californianus</i> may be ‘enhanced’ within the thermal plume of the SBPP. This may be interpreted more properly as an adverse effect on the two species, rather than a beneficial ‘enhancement’.”</p>	<p>Ford does not describe what part of the thermal plume is referenced or how “enhanced” reproduction is “an adverse effect. In this and many other assertions of impacts, Ford omits information on both the location and limit of effects and his understanding and definition of adverse effects.</p>
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